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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,180	01/18/2007	Bruno Balay	0512-1319	5568

466 7590 12/05/2011
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209 Madison Street
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EXAMINER

HOBAN, MELISSA A

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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12/05/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/566,180	Applicant(s) BALAY ET AL.	
	Examiner MELISSA HOBAN	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-13 and 18-26 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-13 and 18-26 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The Amendment filed 11/7/2011 has been entered. The previous rejection under 35 USC 112, 2nd paragraph, is withdrawn in light of applicant's amendments. Claims 1-13 and 18-26 are currently pending in this application.

Response to Arguments

2. Applicant's arguments filed 11/7/2011 have been fully considered but they are not persuasive.

With regard to applicant's argument that Tronzo neither describes nor suggests that the acetabular implants are screwed into the bone, the examiner disagrees. Tronzo teaches coated blades that extend in a circular direction parallel to the diameter of the cup for the purpose of aiding in anchorage by bone growth (col. 2). Though Tronzo does not explicitly teach that the cup is screwed into the bone, the examiner takes the position that the blades of the cups of Tronzo are intended to be introduced into bone material of the acetabulum and are fully capable of being introduced during a screwing action. Therefore, since the acetabular cup of Tronzo meets the claimed structural limitations and is at least fully capable of performing the claimed functional limitations, it meets the claim. Applicant is reminded that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

With regard to applicant's argument that, where some of the coating of Tronzo might inadvertently be applied onto the blades while spraying it onto the surfaces

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between the blades, Tronzo does not meet the amended limitations that the thin coating covers both the equatorial and polar faces and the crests of the screwing means, the examiner disagrees. It is understood by the examiner that the mere process of plasma spraying would result in varied thicknesses of the coating on the implant, including a thick coating on the convex outer portions and a thinner coating on the screw reliefs, and is therefore met by Tronzo. The examiner further notes that there is a lack of any disclosed criticality of the claimed limitations, particularly since applicant's own specification clearly states that the coating on the screw reliefs may be absent (see page 3, lines 1-2); the screw reliefs, such as threads, may have no coating at all (see page 3, lines 17-18); the coating on the sides and edges of threads being reduced *or omitted* (see page 6, lines 20-25); and that it is possible to bring about a practically non-existent coating of the thread cutting face (see page 11, lines 26-29).

3. In the interest of furthering prosecution, the examiner has included a new ground of rejection in addition to maintaining the previous grounds of rejection (see below).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 and 18-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1 and 18 recite the limitation "the thin coating" in line 15 and line 13, respectively. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 1 and 18 recite the limitation "thread bottoms" in line 13 and line 11, respectively. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 1 is wordy and awkwardly written, particularly with regard to the newly added limitations. It is unclear what constitutes the claimed screw relief versus the claimed screwing means. In addition, it is unclear whether the claimed thread bottoms are the same as the convex portions of the outer surface of the cup.

9. Similarly, claims 2-13 and 18-26 are awkwardly written and unclear. The examiner requests that applicant re-examine the claim language and amend accordingly to clarify what applicant intends to claim.

10. Claim 1 recites the limitation "the coating has a lesser thickness on screw reliefs of said screwing means, the thin coating covering both the equatorial and polar faces and crests of the screwing means", in lines 14-17. This limitation appears to be in contradiction with the limitations of claim 5, which depends from claim 1 and requires that the screw reliefs do not have any coating.

11. Similarly, claim 18 recites the limitation "the coating has a lesser thickness on screw reliefs of the threads, the thin coating covering both the equatorial and polar faces and the crests of the threads", in lines 12-15. This limitation appears to be in contradiction with the limitations of claim 23, which depends from claim 18 and requires that the screw reliefs do not have any coating.

12. Claim 18 recites the limitation "screw reliefs" in line 13. There is insufficient antecedent basis for this limitation in the claim. It is unclear how the claimed screw reliefs are related to the threads.

13. Claim 25 recites the same exact limitations as claim 19. Correction is requested.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

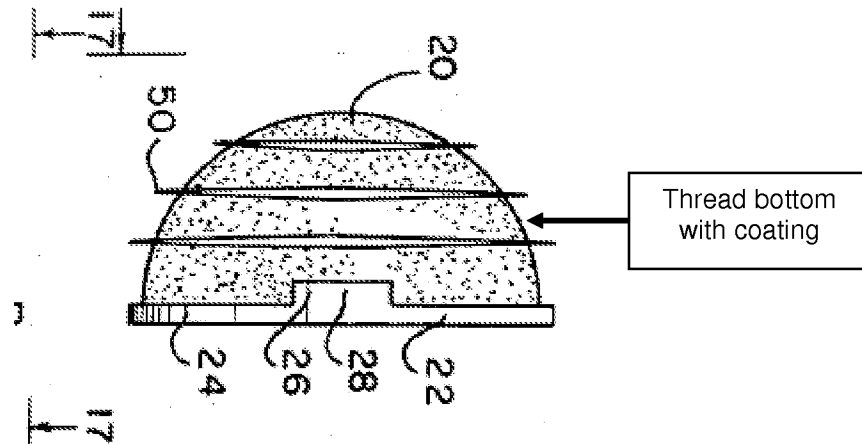
15. Claims 1, 2, 5, 11, 13, 18, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,840,904 to Tronzo (Tronzo) in view of US Patent No. 5,702,473 to Albrektsson et al. (Albrektsson).

Regarding at least claims 1 and 18

Tronzo teaches an acetabular cup prosthesis which has an outer surface having a porous coating and also blades (abstract). The cup (screw cup; 20) is smooth on the inside and preferably receives a liner (articular insert; 22) (col. 2, lines 36-41). The blades are either circular around the cup parallel to the diameter or perpendicular to the diameter or at any angle between these. On the outside of the cup, a porous composition (coating) may be molded on with a view to aiding bone growth to interlock with the cup (col. 2, lines 57-60). The blades may or may not be coated in contrast to the main cup (col. 2, lines 30-35). Figs. 14 and 15 show a form of the invention which has blades (50) on the outside of the cup, the blades extending in a circular direction parallel to the diameter (col. 3, lines 45-49). The circular direction of the blades are construed by the examiner to meet the limitation of screwing means/threads at a periphery and/or in a tropical/equatorial zone of the cup, intended to be introduced into

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bone material of the acetabulum during a screwing action, as claimed by applicant. It is also clear from figs. 14 and 15 that Tronzo meets the limitation that the coating is thick on convex portions of an outer surface of the cup (20), including on thread bottoms of said screwing means. See annotated figure below.



However, Tronzo does not explicitly teach the use of plasma spraying the coating onto the outer surface of the cup.

Albrektsson teaches a cup-shaped member for a hip joint prosthesis that is intended to be screwed into the bone cavity by means of threads (abstract and col. 3, lines 19-22). The entire outer surface of the cup may be roughened or provided with a rough layer of a plasma-sprayed hydroxy-apatite, for the purpose of promoting osseointegration (col. 4, lines 1-3).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Tronzo to substitute the process of molding the coating onto the cup with the process of plasma-spraying the coating, in order to promote osseointegration, particularly since this technique is simple and well known in

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the art for applying a coating on to an implant surface. It is understood by the examiner that the mere process of plasma spraying would result in varied thicknesses of the coating on the implant, including a thick coating on the convex outer portions and a thinner coating on the screw reliefs, covering both the equatorial and the polar faces and the crests of the screwing means, as claimed by applicant, and is therefore met by Tronzo in view of Albrektsson.

The examiner further notes that there is a lack of any disclosed criticality of the claimed limitations, particularly since applicant's own specification clearly states that the coating on the screw reliefs may be absent (see page 3, lines 1-2); the screw reliefs, such as threads, may have no coating at all (see page 3, lines 17-18); the coating on the sides and edges of threads being reduced *or omitted* (see page 6, lines 20-25); and that it is possible to bring about a practically non-existent coating of the thread cutting face (see page 11, lines 26-29).

With regard to the functional language used throughout the claims, the examiner notes that the device of Tronzo is fully capable of meeting the claimed functions and that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding at least claims 2, 5, 11, 13, 20, and 23

Tronzo in view of Albrektsson teaches the invention substantially as claimed according to claims 1 and 18. As explained above, the blades of Tronzo may or may not be coated in contrast to the main cup (col. 2, lines 30-35) and therefore meet the

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limitation of not having any coating, as claimed. The examiner takes the position that at least the sharpness of the blade (screw reliefs; 50) meets the limitation of having a rough surface, as claimed by applicant. It can also be seen from these figs 14 and 15 of Tronzo that the screwing means has a spherical threading which appears to be of constant pitch, as claimed by applicant. Tronzo further appears to meet the limitation of having a regular threading pitch, as claimed by applicant, since the definition of regular is: conforming to a standard or pattern, which Tronzo's threading pitch clearly does.

Tronzo also teaches that the porous material should be at least 100 microns thick, preferably at least 1/16 inch thick and most desirably at least 1/8 inch thick (col. 3, lines 54 and col. 4, lines 1-3), thereby meeting the limitation that the thick coating has a thickness from 100 to 200 micrometers, as claimed.

With regard to the functional language used throughout the claims, the examiner notes that the device of Tronzo is fully capable of meeting the claimed functions and that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

16. Claims 3, 4, 19, 21, 22, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo in view of Albrektsson, as applied to claims 1, 2, 18, and 20 above, and further evidenced by US Patent Application Publication No. 2005/0267585 A1 to Sidebotham (Sidebotham).

Regarding at least claims 3, 19, 21, and 26

Tronzo in view of Albrektsson teaches the invention substantially as claimed according to claims 1, 2, 18, and 20. However, Tronzo in view of Albrektsson does not explicitly teach a thickness of the thick coating of an order of 150 +/- 35 micrometers. Tronzo in view of Albrektsson also does not explicitly teach a selective calcium hydroxyapatite coating.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the thickness taught by Tronzo in view of Albrektsson to specify that the coating is of an order of 150 +/- 35 micrometers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Further, it would have been obvious to specify this range of thickness since this range of thickness is well known in the art for coatings on acetabular shells, as evidenced by Sidebotham (paragraph 0038, lines 1-7), particularly in view of the lack of any disclosed criticality of the claimed limitations (see page 3 of applicant's specification which clearly states that these thicknesses are not limiting and that they are dependent on the type and quality of the osteointegrating coating).

It also would have been obvious to one having ordinary skill in the art at the time of the invention to specify that the porous composition taught by Tronzo in view of Albrektsson is a selective calcium hydroxyapatite coating, since this type of coating is well known in the art as a porous composite and has been used in combination with implants, in order to allow for bone-growth resulting in firm attachment.

Regarding at least claims 4 and 22

Tronzo in view of Albrektsson teaches the invention substantially as claimed according to claims 1 and 18. As explained above, Tronzo teaches that the blades (screw reliefs; 50) may or may not be coated in contrast to the main cup (col. 2, lines 30-35). However, Tronzo in view of Albrektsson does not teach an order of coating of 50 +/- 30 micrometers on the screw reliefs.

Tronzo further teaches that a portion of the porous composite having a thickness, for example, of about 100 micrometers, as taught by Tronzo (col. 4, line 1), may be inadvertently sprayed onto the blades resulting in a thickness on the blades of less than 100 micrometers, thereby potentially meeting the claimed range, particularly in view of the lack of any disclosed criticality of the claimed limitation (see applicant's specification on pages 3, 6, and 11, which indicate that the coating on the screw reliefs may be absent).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Tronzo to include that the coating of the blades is of an order of 50 +/- 30 micrometers, since a portion of the porous composite having a thickness, for example, of about 100 micrometers, as taught by Tronzo (col. 4, line 1), may be inadvertently sprayed onto the blades resulting in a thickness on the blades of less than 100 micrometers, thereby meeting the claimed range, particularly in view of the lack of any disclosed criticality of the claimed limitation (see applicant's specification on pages 3, 6, and 11, which indicate that the coating on the screw reliefs may be absent). It also would have been obvious, since it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

17. Claims 6, 7, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo in view of Albrektsson, as applied to claims 1 and 18, and further in view of US Patent No. 4,883,491 to Mallory et al. (Mallory).

Regarding at least claims 6 and 24

Tronzo in view of Albrektsson teaches the invention substantially as claimed according to claims 1 and 18. However, Tronzo in view of Albrektsson does not explicitly teach that the screw reliefs are arranged to apply a self-tapping cutting effect during the screwing action and effect compression of the bone material.

Mallory teaches a porous-coated, threaded acetabular cup (screw cup; 10) including a self-tapping screw thread (screwing means; 16) (col. 2, lines 46-56 and col. 3, lines 36-38). The thread (16) is formed on the outer surface of the body (18) by milling the surface and is preferably a spherical thread that includes leading edges (30) which are sufficiently sharp for the thread to be self-tapping (col. 3, lines 55-61 and fig. 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the screw cup of Tronzo in view of Albrektsson to include a self-tapping cutting effect during the screwing action and effect compression of the bone material, in order to provide an ability to advance when turned, while creating its own thread, particularly since these screw types are well known in the art.

With regard to the functional language used throughout the claims, the examiner notes that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding at least claim 7

Tronzo in view of Albrektsson and further in view of Mallory teaches the invention substantially as claimed according to claim 6. Though Tronzo in view of Albrektsson and further in view of Mallory does not appear to explicitly teach a proportion of thread width relative to a thread pitch from 0.2 to 0.5, the examiner takes the position that it would have been obvious to include such proportions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It also would have been obvious particularly in view of the lack of any disclosed criticality of the claimed limitation (see page 4 of applicant's specification which implies that this proportion is not material to the patentability of the invention).

18. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo in view of Albrektsson, as applied to claim 1, and further in view of Mallory, as evidenced by US Patent No. 5,443,520 to Zweymuller et al. (Zweymuller).

Tronzo in view of Albrektsson teaches the invention substantially as claimed according to claim 1. However, Tronzo in view of Albrektsson does not teach an asymmetrical cross-section of the threads in a diameter plane.

As explained above, Mallory teaches that the thread (16) is formed on the outer surface of the body (18) by milling the surface and is preferably a spherical thread that includes leading edges (30) which are sufficiently sharp for the thread to be self-tapping (col. 3, lines 55-61 and fig. 1). Though Mallory does not appear to explicitly teach angles of the threads with respect to the outer surface of the cup, Mallory does teach that the cup includes a self-tapping screw thread having a cross-section which appears to be asymmetrical in a diametral plane, at least to the same extent applicant's is, with a smaller angle at the polar side of the thread and a greater angle at an equatorial side (fig. 3).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Tronzo in view of Albrektsson and further in view of Mallory to include specifics about the threads, such as angles, in order to include threads having a size, thickness, and height adapted to the size of the socket component for use so that the operator, during surgery, can select a cup matched to the quality of bone material in the pelvic region, as evidenced by Zweymuller (col. 6, lines 15-26). It also would have been obvious to specify the angles of the threads on the polar side and on the equatorial side, particularly in view of the absence of any disclosed criticality of the claimed limitations. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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19. Claims 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo in view of Albrektsson, as applied to claim 1, and further in view of US Patent No. 5,147,407 to Tager (Tager).

Tronzo in view of Albrektsson teaches the invention substantially as claimed according to claim 1. However, Tronzo in view of Albrektsson does not explicitly teach that the crests of threads are relieved or that the leading edge is inclined.

Tager teaches a prosthetic cup member having an outer surface with coaxial threads interrupted by grooves extending transversely to the thread. The threads are self-tapping threads and are formed to permit the threaded outer shell to be screwed into the bone (abstract). Tager further teaches that openings (inclined grooves; 11) are milled at an angle with respect to the axis and at an angle with respect to the radius, i.e. the walls of the openings are inclined towards the rotational direction of outer shell (10) (col. 3, lines 1-9). The discrete thread portions (12) form a plurality of rows (zones; 13) at an angle to the axis of outer shell (10) between openings (11). Since the device taught by Tager is made in the same way as applicant's, it is inherent that it also includes crests with leading edges of threads that are radially higher than the remainder of the crest, and which leading edges are themselves inclined by being formed by a milling pass, as claimed by applicant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Tronzo in view of Albrektsson to include crests of threads that are relieved or that the leading edge is inclined in order to facilitate

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insertion of the cup and improve its anchoring after emplacement, as taught by Tager (col. 2, lines 14-20).

20. In addition to the above rejection, claims 1-13 and 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,702,473 to Albrektsson et al. (Albrektsson), as evidenced by US Patent No. 5,478,237 to Ishizawa (Ishizawa) and US Patent Application Publication No. 2005/0267585 A1 to Sidebotham.

Regarding at least claims 1 and 18

Albrektsson teaches an acetabular cup (screw cup; 1) intended to hold a complimentary liner (acetabular liner). The cup comprises two main parts, a spherical segment (2) and a cylindrical part (3), the outside of which is provided with a circumferential bead which is in the form of a thread (screwing means; 5). The pitch (D) of the thread may be about 2 mm and of the height (H) about 1 mm in a normal sized cup. In this way, Albrektsson teaches that the thread will have the shape of a barb or a saw tooth. When the cup is pushed into a cavity in the bone tissue, the thread consequently will allow the cup to be moved into the cavity but will prevent the cup from being moved out from the cavity (col. 2, lines 19-38). The cup will be screwed inwards into the cavity by means of the threads which are being cut, which means that the cup will be pressed inwards against the surface of the cavity (col. 3, lines 19-22). It is understood by the examiner that Albrektsson meets the limitations of a screw cup configured to receive an acetabular insert, screwing means at a periphery or in a tropical/equatorial zone of the cup, said screwing means are intended to be introduced into bone material of the acetabulum during screwing action, as claimed by applicant.

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The thread (screwing means; 5) of Albrektsson is considered to inherently comprise screw reliefs, each screw relief having a polar face, an equatorial face, and a crest, as claimed.

Albrektsson also teaches a roughness on the entire outer surface of the cup, including the cylindrical part (3) and the threads (5) (col. 2, lines 44-45), which can be obtained by plasma spraying and/or by providing the surface with a rough layer of some other material than the material in the cup, such as a plasma sprayed layer of hydroxyapatite. The additional layer advantageously might be an osseointegration promoting or growth-stimulating material. The rough surface also could be provided with a thin layer or be treated with a growth-stimulating agent (col. 3, lines 48-55 and col. 4, lines 1-4). Therefore, Albrektsson meets the limitations of a coating carried by the cup, said coating facilitating osseointegration, as claimed by applicant. It is also understood by the examiner that the coating on the entire surface of the cup taught by Albrektsson covers the convex portions of the outer surface of the cup, including on thread bottoms and on screw reliefs of said screwing means covering both the equatorial and polar faces and the crests of the screwing means, as claimed by applicant.

Though Albrektsson does not explicitly teach a coating thickness, the examiner takes the position that a thicker coating on the convex portions of the outer surface of the cup, including on thread bottoms, and a coating of lesser thickness on the screw reliefs, covering the equatorial and polar faces, and the crests of the screwing means, is inherent to a coating applied by plasma spraying, as taught by Albrektsson, particularly since it is well known in the art that it is very difficult to uniformly and firmly coat an

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implant having any complicated shape with biologically active material. For example, by the plasma-spray technique, it is relatively easy to coat the outer surface of an implant; however, it is very difficult to coat the whole surface uniformly with such biologically active material, as evidenced by Ishizawa (col. 2, lines 15-28). Ishizawa provides an implant that includes threads on the base body wherein the base body is provided with a porous surface layer formed by plasma-spraying (col. 4, lines 29-38). Though Ishizawa does not explicitly teach an acetabular implant, the examiner takes the position that these two teachings are in the same field of endeavor and reasonably pertinent to the particular problem with which the applicant was concerned, namely applying a coating to an implant via plasma-spray technique.

Regarding at least claims 2, 3, 11, 13, 19-21, 25, and 26

Albrektsson teaches the invention substantially as claimed according to claims 1 and 18. Albrektsson also teaches that the coating is a hydroxy-apatite and further appears to meet the limitation of having a regular threading pitch, as well as a spherical threading of constant pitch (col. 2, lines 32-35 and fig. 4), as claimed by applicant. However, Albrektsson does not explicitly teach a thickness of the thick coating from 100 to 200 micrometers or of an order of 150 +/- 35 micrometers. Albrektsson also does not explicitly teach a selective calcium hydroxyapatite coating.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the thickness taught by Albrektsson to specify that the coating is from 100 to 200 micrometers or of an order of 150 +/- 35 micrometers, since it has been held that where the general conditions of a claim are disclosed in the prior art,

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discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Further, it would have been obvious to specify this range of thickness since this range of thickness is well known in the art for coatings on acetabular shells, as evidenced by Sidebotham (paragraph 0038, lines 1-7), particularly in view of the lack of any disclosed criticality of the claimed limitations (see page 3 of applicant's specification which clearly states that these thicknesses are not limiting and that they are dependent on the type and quality of the osteointegrating coating).

It also would have been obvious to one having ordinary skill in the art at the time of the invention to specify that the porous composition taught by Albrektsson is a selective calcium hydroxyapatite coating, since this type of coating is well known in the art as a porous composite and has been used in combination with implants, in order to allow for bone-growth resulting in firm attachment.

Regarding at least claims 4, 5, 22, and 23

Albrektsson teaches the invention substantially as claimed according to claims 1 and 18. As explained above, Albrektsson teaches that the threads (screw reliefs; 5) are coated. However, Albrektsson does not teach an order of coating of 50 +/- 30 micrometers on the screw reliefs or that the screw reliefs do not have any coating and have a rough surface.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Albrektsson to include that the coating of the threads is of an order of 50 +/- 30 micrometers, since it is understood that the process of plasma spraying would result in a thinner coating on the threads than on the outer

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convex portions of the cup, and since it is well known in the art that it is very difficult to provide a uniform coating via the plasma-spray technique, as evidenced by Ishizawa.

The examiner takes the position that the process of plasma spraying could also result in the screw reliefs not having any coating, if desired and depending on the various factors of the nozzle in relation to the screw reliefs (threads). It is also understood by the examiner that the threads, themselves, meet the limitation of a rough surface, as claimed.

21. Claims 6, 7, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrektsson in view of US Patent No. 4,883,491 to Mallory et al. (Mallory).

Albrektsson also does not teach a thread pitch ratio, an asymmetrical cross-section of the threads, or successive threads.

Regarding at least claims 6 and 24

Albrektsson teaches the invention substantially as claimed according to claims 1 and 18. However, Albrektsson does not explicitly teach that the screw reliefs are arranged to apply a self-tapping cutting effect during the screwing action and effect compression of the bone material.

Mallory teaches a porous-coated, threaded acetabular cup (screw cup; 10) including a self-tapping screw thread (screwing means; 16) (col. 2, lines 46-56 and col. 3, lines 36-38). The thread (16) is formed on the outer surface of the body (18) by milling the surface and is preferably a spherical thread that includes leading edges (30) which are sufficiently sharp for the thread to be self-tapping (col. 3, lines 55-61 and fig. 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the screw cup of Albrektsson to include a self-tapping cutting effect during the screwing action and effect compression of the bone material, in order to provide an ability to advance when turned, while creating its own thread, particularly since these screw types are well known in the art.

With regard to the functional language used throughout the claims, the examiner notes that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding at least claim 7

Albrektsson in view of Mallory teaches the invention substantially as claimed according to claim 6. Though Albrektsson in view of Mallory does not appear to explicitly teach a proportion of thread width relative to a thread pitch from 0.2 to 0.5, the examiner takes the position that it would have been obvious to include such proportions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It also would have been obvious particularly in view of the lack of any disclosed criticality of the claimed limitation (see page 4 of applicant's specification which implies that this proportion is not material to the patentability of the invention).

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22. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albrektsson in view of Mallory, and further in view of US Patent No. 6,146,425 to Hoermansdoerfer (Hoermansdoerfer).

Albrektsson teaches the invention substantially as claimed according to claim 1. However, Albrektsson does not teach an asymmetrical cross-section of the threads in a diameter plane.

As explained above, Mallory teaches that the thread (16) is formed on the outer surface of the body (18) by milling the surface and is preferably a spherical thread that includes leading edges (30) which are sufficiently sharp for the thread to be self-tapping (col. 3, lines 55-61 and fig. 1). Though Mallory does not appear to explicitly teach angles of the threads with respect to the outer surface of the cup, Mallory does teach that the cup includes a self-tapping screw thread having a cross-section which appears to be asymmetrical in a diametral plane, at least to the same extent applicant's is, with a smaller angle at the polar side of the thread and a greater angle at an equatorial side (fig. 3).

Hoermansdoerfer teaches a screw-in type artificial hip joint including a spherical shell shape and revolving thread procession sectionally represented by individual teeth (A, B, C, D, E) which are distributed in series from the equatorial edge of the socket to the pole (col. 7, lines 51-58). The pole side flank (12) of the thread tooth is tilted away with an angle of 10° and the corresponding side angle of the tooth flank (13) is 32° (col. 8, lines 44-48 and fig. 2), in order to ensure an effortless screwing, a stable seat in the long term and an unproblematic explanation (abstract). Though Hoermansdoerfer does

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not explicitly teach an angle from 15 to 20°, the examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the angle of Hoermansdoerfer, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Albrektsson in view of Mallory, to include angles of the threads, in order to ensure an effortless screwing, a stable seat in the long term and an unproblematic explanation, as taught by Hoermansdoerfer.

23. Claims 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrektsson in view of US Patent No. 5,147,407 to Tager (Tager).

Albrektsson teaches the invention substantially as claimed according to claim 1. However, Albrektsson does not explicitly teach that the crests of threads are relieved or that the leading edge is inclined.

Tager teaches a prosthetic cup member having an outer surface with coaxial threads interrupted by grooves extending transversely to the thread. The threads are self-tapping threads and are formed to permit the threaded outer shell to be screwed into the bone (abstract). Tager further teaches that openings (inclined grooves; 11) are milled at an angle with respect to the axis and at an angle with respect to the radius, i.e. the walls of the openings are inclined towards the rotational direction of outer shell (10) (col. 3, lines 1-9). The discrete thread portions (12) form a plurality of rows (zones; 13) at an angle to the axis of outer shell (10) between openings (11). Since the device

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taught by Tager is made in the same way as applicant's, it is inherent that it also includes crests with leading edges of threads that are radially higher than the remainder of the crest, and which leading edges are themselves inclined by being formed by a milling pass, as claimed by applicant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Albrektsson to include crests of threads that are relieved or that the leading edge is inclined in order to facilitate insertion of the cup and improve its anchoring after emplacement, as taught by Tager (col. 2, lines 14-20).

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The reference US Patent No. 5,972,032 to Lopez et al. shows an acetabular component (70) having a shell wall defined by a convex proximal surface (74) provided with a macro-texture comprising grooves (87), filled and covered by a porous coating layer (88) are known in the art. The porous coating layer (88) provides a rough and porous surface that mechanically engages bone and accepts ingrowth or ongrowth of bone (col. 5, lines 32-59). It can be seen from fig. 10 shows that the coating (88) is thicker on the convex portions of the outer surface of the cup and has a lesser thickness on screw reliefs (see fig. 10 below).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA HOBAN whose telephone number is

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(571)270-5785. The examiner can normally be reached on Monday through Friday (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Thomas Sweet, at (571) 272-4761***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

[TC3700 Workgroup D_Inquiries@uspto.gov](mailto:TC3700_Workgroup_D_Inquiries@uspto.gov).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 3738

/BRUCE E SNOW/
Primary Examiner, Art Unit 3738